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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,691	04/26/2001	Eui-Sung Choi	118.12-US-WO	9629

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,691	CHOI ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-13 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/3/01</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. Specifically, sequences are present in the Figures which are not identified by the appropriate SEQ ID NO: identifiers in the Brief Description of the Drawings or in the Drawings themselves.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Any response to this Office Action which does not include complete compliance with the Sequence Rules will be considered non-responsive.

Specification

A substitute specification, **excluding the claims**, in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. The instant specification appears to be a literal translation from the Korean and therefore a substitute specification in proper idiomatic English is required to clarify the language in the instant disclosure.

35 USC 102 Rejections

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (cited by applicants).

Applicants claim a L41 gene encoding a *Phaffia rhodozyma* ribosomal protein (a cycloheximide resistant gene) whose amino acid sequence is described by SEQ ID NO: 3. Applicants also recite the genomic (SEQ ID NO:1) and cDNA (SEQ ID NO:2) versions of the L41 gene of *P. rhodozyma*. Applicants claim the *P. rhodozyma* L41 gene wherein the codon for the amino acid (proline) at position 56 is replaced with a codon representing glutamine, a vector (pTPLR1) comprising said gene and a portion of *P. rhodozyma* ribosomal DNA as well as a method for transforming yeast comprising linearizing the vector and transforming the yeast by electroporation under an electric pulse of 0.8~1.2 kV, an internal resistance of 400~800 Ω and a capacitance of 25~50 μ F.

Kim et al. (Appl. Environ. Microbiol., May 1998, Vol. 64, No. 5, pp. 1947-1949, see whole article, particularly the Abstract; p. 1947; Figs. 1-2; the first 3 full paragraphs on p. 1948 and the last paragraph on p. 1949) discloses the same *P. rhodozyma* L41 gene (deposited under the same GenBank Accession Number (AF004672) as instantly recited as well as the cycloheximide resistant mutant comprising a substitution of proline at position 56 with a glutamine. The claimed amino acid sequence encoded by the *P.*

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rhodozyma L41 gene is inherent in the nucleic acid recited by Kim et al. and Kim et al. define the exons of the *P. rhodozyma* L41 gene and the cDNA of the gene is also disclosed. Kim et al. disclose the pTPLR1 vector and the claimed method for transformation (by electroporation under the claimed conditions) of a yeast (*C. neoformans*) with said vector. Kim et al. also recites that the transformation procedure outlined can be used to transform *P. rhodozyma* with the L41 gene as a selectable marker for cycloheximide resistance.

It is noted that a comparison of the nucleotide sequence of the *P. rhodozyma* L41 gene disclosed in the instant application with the nucleotide sequence of the molecule deposited under AF004672 indicates a discrepancy involving the nucleotides between positions 768-782. Since both the instant application and the Kim et al. reference refer to the **same nucleic acid sequence deposited under the same GenBank accession number**, it must be considered that the two sequences are identical and the discrepancy in the sequence referred to by applicants and Kim et al. is, absent evidence to the contrary, the result of a mistake in sequencing or manually writing down the recited sequence.

The May 1998 issue of Appl. Environ. Microbiol. (Vol. 64, No. 5) was received by the PTO Biotech Library on May 5, 1998. The disclosure of Kim et al. was therefore publicly available more than one year prior to the 35 USC 120 filing date (5/29/99).

35 USC 101 Rejections

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants claim the recited L41 genes and ribosomal DNA of *P. rhodozyma* in their natural milieu, that is the claimed nucleic acid sequences are not recited as isolated or recombinant and hence read on the nucleic acids in *P. rhodozyma* cells. With regard to Claim 4, this reads on a naturally occurring mutation.

Foreign Priority Document

Applicants have not filed a translation of the Korean priority document. However, an examination, to the extent possible, of the text and drawings in said document indicates that the claimed sequences and vectors are present in said document.

Claims 5 and 8 are free of the art because the *P. rhodozyma* ribosomal DNA sequence recited in the claims (SEQ ID NO:4) is not taught by the prior art.

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571)

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272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
January 20, 2005


DAVID GUZO
PRIMARY EXAMINER